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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,605	12/09/2003	David James Dooley	PC25026A	4759

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,605	DOOLEY ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-11,13-16 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,17-18,20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are presented for examination.

Applicant's Amendment filed September 6, 2006 has been received and entered into the present application.

Claims 1-20 are pending. Claims 12, 17-18 and 20 are under examination and claims 1-11, 13-16 and 19 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b). Claim 17 is amended.

Applicant's arguments, filed September 6, 2006, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 17-18 and 20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brummel et al. (WO 01/01983; 2001), already of record, for the reasons of record set forth at page 4 of the previous Office Action dated June 6, 2006, of which said reasons are herein incorporated by reference.

Applicant asserts that Brummel et al. refers only to the use of a combination of pregabalin and gabapentin to treat several different types of pain, including pain associated with restless leg syndrome. Applicant alleges that treatment of the unpleasant sensations or "pain" associated with restless legs syndrome cannot anticipate or even render obvious the treatment of restless legs syndrome because

efficacy for the treatment of restless legs syndrome involves more than producing an analgesic effect. Applicant relies upon the fact that both the International Restless Legs Rating Scale and the Clinical Global Impression of Improvement Scale, each of which is used to rate symptoms and their daily impact, do not contain any questions related to pain. Applicant further relies upon the fact that the data presented to the FDA in support of the approval of the drug Requip® contained data from each of these scales in support of their position.

Applicant's remarks have been carefully considered in their entirety, but fail to be persuasive.

First, in response to Applicant's statement that Brummel et al. teaches the treatment of several different types of pain, one of which is pain associated with restless legs syndrome, Applicant is advised that fact that Brummel et al. may teach the treatment of other types of pain does not teach away from the fact that the disclosure of the reference explicitly set forth the treatment of pain associated with restless legs syndrome as being amenable to treatment with pregabalin. Applicant's attention is directed to the MPEP at §2131.02 (see "A Reference That Clearly Names the Claimed Species Anticipates the Claim No Matter How Many Other Species Are Named"), which states, "A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. 102(a), in that publication.'). Id. at 1718. See also *In re Simvaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)."

Applicant's allegation that the treatment of pain associated with restless legs syndrome is not sufficient to anticipate the presently claimed method of treating restless legs syndrome by administering pregabalin (page 11, Applicant's remarks) is not persuasive. The fact that Brummel et al. expressly contemplates the administration of pregabalin and gabapentin to treat the pain resulting from restless legs syndrome in a patient obviously suffering from restless legs syndrome is clearly adequate direction to anticipate the presently claimed method of treating restless legs syndrome using pregabalin. The fact that Brummel et al. may teach that the combination of pregabalin and gabapentin is sufficient to ameliorate at least one condition (i.e., pain) that directly results from the condition of restless legs syndrome is an express and unequivocal teaching of the treatment of restless legs syndrome *per se* in a patient in need of such treatment by administering the claimed active pharmaceutical agent.

Applicant appears to be drawing a distinction between the presently claimed method and the teachings of Brummel et al. by stating that, "Treatment of the unpleasant sensations or 'pain' associated with restless legs syndrome cannot anticipate or even render obvious the treatment of restless legs syndrome because efficacy for the treatment of restless legs syndrome involves more than producing an analgesic effect." However, Applicant has solely claimed the "treatment of restless legs syndrome", not the comprehensive treatment, or in an extreme sense, cure, of the entire syndrome itself. An ordinary and customary use of the term "treatment" is reasonably understood to mean any amelioration or improvement of such a disease or disorder and/or the symptoms or conditions that directly result from and, therefore, characterize, the same disease or disorder. Accordingly, any improvement in the pain that is associated with restless legs syndrome so as to produce an analgesic effect necessarily treats, i.e., improves or ameliorates, the condition of restless legs syndrome as a whole.

Furthermore, the fact that Brummel et al. expressly teaches the administration of the identical compound (i.e., pregabalin) to an identical host (i.e., a patient suffering from restless legs syndrome), the "treatment" of restless legs syndrome is clearly taught by the reference. Brummel et al. teaches that the

skilled artisan was already aware of the occurrence of the desired therapeutic effect in treating restless legs syndrome using pregabalin, even if the therapeutic objective of the patentee was to treat the pain associated with such a syndrome.

Applicant further maintains that the fact that the International Restless Legs Syndrome Rating Scale and the Clinical Global Impression of Improvement Scale do not contain questions related to pain is additional evidence that the treatment of pain associated with restless legs syndrome is not suggestive of the treatment of restless legs syndrome as a whole. This is not found persuasive. The fact that the art may use two different types of rating scales in order to assess the severity and frequency of symptoms and the quality of life of patients suffering from such a condition does not serve in any manner to negate the teachings of the cited reference to Brummel et al. Accordingly, this evidence is not persuasive in establishing error in the propriety of the present rejection.

Furthermore, Applicant states on the record that, "While this disorder involves unpleasant sensations in the legs of patient that create an urge to move the patient's legs, it is not considered a pain syndrome or disorder" (page 11, Applicant's remarks). However, in view of the fact that Applicant provides no evidence to this effect, such a statement amounts to no more than an allegation by Applicant and is not persuasive. Please reference MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)." In addition, it is noted that such a statement attempts to draw a conclusion that no patient suffering from restless legs syndrome exists in the art who finds these "unpleasant sensations" painful. Applicant is reminded that nociception and pain thresholds vary from individual to individual and, therefore, the "sensations" that patients suffering from restless legs syndrome experience may be uncomfortable to one person and extraordinarily painful to another. In light of such, Applicant's blanket statement that restless legs syndrome is not a pain disorder is unsubstantiated by any evidence and is clearly not persuasive.

For these reasons described *supra*, the teachings of Brummel et al. clearly anticipate the presently claimed method for treating restless legs syndrome comprising the administration of pregabalin to a patient in need thereof. Accordingly, Applicant's arguments are not persuasive and claims 12, 17-18 and 20 remain properly rejected for the reasons of record.

Conclusion

Rejection of claims 12, 17-18 and 20 remains proper and is **maintained**.

Claims 1-11, 13-16 and 19 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

December 6, 2006

12/8/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER